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14. ABSTRACT
Substance use disorders (SUD) and posttraumatic stress disorder (PTSD) are prominent disorders among Service Members (SMs). These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) is an evidence-based model for comorbid SUD/PTSD. This study evaluates the SS manual and Adherence Scale in a military setting. We have completed this project, including obtaining all necessary IRB/HRPO approvals,; collecting all phase 1 data: analyzing that data (with findings of significant positive outcomes, which is currently under revision as a journal article): presenting the phase 1 data at several national conferences: collecting phase 2 data (which did not diverge from the phase 1 data): created the military monograph (aka "supplement") and adherence scale, created an additional deliverable that was not in the original SOW but appears highly useful to the project (a SS military/veteran website): and produced a large number of scientific publications during the study period.

15. SUBJECT TERMS
PTSD, Substance Use Disorder, Seeking Safety

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INTRODUCTION

Substance use disorders (SUD) and posttraumatic stress disorder (PTSD) are some of the most prominent psychiatric disorders among Service Members (SMs), including the Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) cohort. These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) has been established as an effective model for co-occurring SUD/PTSD. The purpose of this study is to evaluate the SS manual and Adherence Scale for implementation in a military setting. We hypothesize that the Seeking Safety manual and Adherence Scale can be successfully used in the military setting, with "success" defined as 80% or higher satisfaction and feasibility on this project by at least 80% of participants.

BODY

Following each task listed in the Statement of Work, we provide a description of our progress on that task.

STATEMENT OF WORK

Task 1: Study startup (months 1-6)
Apply for human subjects approval at each site

Human subjects approval update

1. The project received IRB approval by the Walter Reed National Military Medical Center (WRNMMC) as a data location site and by the New England IRB for Treatment Innovations (the latter for data analysis). The study was re-approved for Continuing Review annually for each location and was formally closed in 2014 at both locations as all scientific goals had been accomplished and the manuscript resulting from this trial was under revew.

Note: the original plan was for additional data collection sites, but those sites never became part of the study due to changes in personnel (e.g., our point of contact left, or the administration changed direction regarding the study). Thus, the study data collection was donc solely at WRNMMC.

3. The CRADA between WRNMMC and TI for this project was approved 9/13/12.

4. The study was on no-cost extension for two years. This is needed due to the very slow initial study start-up based on multiple rounds of IRB delays.

Establish regular conference calls with sites

WRNMMC and TI (all study-related personnel) had regular calls and email updates ongoing throughout the project related to conduct of the study. Also, the PI (Dr. Najavits) held one conference call with study clinicians at WRNMMC as part of the development of the military monograph.

Train staff as needed

All staff were trained successfully for their duties on this project. This included research assistant, study clinicians, and project managers. Also, due to another DoD grant (W81XWH1020074) that was simultaneous with this one, we are able to leverage the RAs' time to work on this study as many of the RA tasks converged for the two projects.

Develop data entry procedures for on-going data entry

We worked with the WRNMMC site to establish secure procedures for transmission of data from WRNMMC to TI, via the AMRDEC Safe Access File Exchange (https://safe.amrdec.army.mil/safe/). TI received ongoing de-identified data through that method, and TI performed quality review checks on the data. Data entry occurred at WRNMMC by the site RA there (Ms. Stephanie Southard).

Set up systems for tracking data progress

All data tracking was conducted by collaboration between WRNMMC and TI, including assessment completion logs on each patient.

Set up standard operating procedures

We had strong and efficient systems in place for all study tasks. All study personnel contributed to those efforts.

Begin the initial Delphi procedure with our consultant team

We conducted a version of the Delphi procedure with study clinicians (rather than the consultants originally listed on the project). As the study clinicians know the military environment and directly worked with the patients using SS, this appeared more helpful. It also helped to preserve study funds as the study has continued beyond the original planned timeframe. The study clinicians also continually added to the the General Feedback log to record any comments they had regarding conducting the SS therapy. We focused our qualitative efforts largely toward the military monograph, which became a key, lasting product of this project (see that section below).

Task 2: Adapt the SS manual and adherence scale for military use (months 6-22)

Completed. See details below.

Months 7-8: obtain T1 assessment on the first half of the sample of clients and clinicians; then provide them with SS materials.

Completed. See details below.

Months 9-10: create the initial draft of the military SS monograph and adherence scale (based on feedback obtained in prior months).

Completed. See details below.

Months 10-11: Obtain T2 assessment from first half of sample.

Completed. See details below.

Months 11-13: obtain T1 assessment from the second half of the sample; and continue Delphi procedure with consultants.

In process. See details below.

Military monograph

1. The PI held multiple conference calls with study clinicians at WRNMMC to as part of the development of the military monograph in the past year. Also, she worked closely with the site PI to edit it as needed for the site. Note: the "military monograph" was renamed the "military supplement" at the request of the site PI.

2. The Military Supplement was completed in early April 2013 after a thorough review of outcome, feasibility, and satisfaction data from Phase 1 of the "Seeking Safety for Service Members" study. This document aims to assist clinicians that use the Seeking Safety treatment manual with active duty service members by providing examples related to military stressors and situations, addressing different phases of military involvement (e.g., pre-deployment, deployment, and post-deployment), and using language typical in military settings. The WRNMMC IRB approved the supplement for use in phase 2 of the study.

3. The SS Adherence Scale was modified, per the SOW, for military use. The WRNMMC IRB approved the revised scale for use in phase 2 of the study.

4. The PI also created an SS military/veteran website with additional material outside of the Military Supplement. This is an additional deliverable that was not in the original SOW but appears highly useful to the project as it provides extra information and materials that can be readily updated and can collect ongoing feedback (anonymously or nonanonymously). This website can be accessed at: www.seekingsafety.org/military. The username (login) is guest, and the password is guest (both lowercase, same word). The website will be freely accessible without a password beginning October 1, 2014 (there was a delay in moving the existing Seeking Safety to a new technology platform, but that will occur by the above date, at which point the military website will be a sub-page on it).

Data collection

1. Phase 1: data collection for phase 1 was begun and completed as a quality improvement project, with over two hundred patients attending Seeking Safety sessions during Phase 1.

Feedback on at least one individual Seeking Safety topic was received from over eighty-three clients and twenty-nine clinicians. Twenty-five clients completed Phase 1 of the study by receiving 8 or more topics in either individual or group sessions. Ten clinicians completed Phase 1 of the study by June 2012 (due to either completion of at least 20 topics or termination of employment).

2. Phase 2: data collection for phase 2 began on 1 May 2013 and was completed, reaching the recruitment goal of 20 service members,,at the end of December 2013. This phase of the project was designed to evaluate outcome, feasibility, and satisfaction of the Military Supplement used in conjunction with the Seeking Safety treatment manual.

KEY RESEARCH ACCOMPLISHMENTS:

- Obtained all necessary IRB and HRPO approvals, and also reapprovals/continuations as needed.

- Successfully created secure procedures for data transmission between WRNMMC and TI.

- Had an outstanding team at each location, with ongoing communication, strong morale, which worked effectively across sites.

- All staff were successfully trained, including study clinicians, research assistants, and project director.

- Completed phase 1 data collection, which evidenced significant results. Findings were written up for publication and submitted to the journal, *Military Medicine* in 2014. In July, 2014 the journal provided feedback and encouraged resubmission. See the Appendix for the manuscript. The revision for *Military Medicine* will be finalized and sent in October, 2014.

- Results of this project were presented at multiple professional conferences. See Appendix for the powerpoint and a list of the presentations.

- We obtained formal clearance from WRNMMC to present the findings per the 2 bullet points above.

- Created military monograph (now called "military supplement") and obtained IRB approval at WRNMMC to use it in phase 2 of the study.

- Phase 2 data collection was completed as planned. As results did not show any difference from phase 1, no publication was based on that.

- We applied for no-cost extensions for the study so that we could successfully complete all SOW tasks. This was needed due to the very slow initial study start-up based on

multiple rounds of IRB delays, changes in study staff, loss of some original planned additional study sites, as well as the move of WRNMMC from Washington, DC to Bethesda, MD. With these extensions, we were able to complete all of the original scientific aims of the project.

- Created a Seeking Safety military/veteran website as an additional resource directly related to this project. This was not stated in the study SOW but during the course of the study it became clear that it would make an excellent lasting product from this study. This website can be accessed at: www.seekingsafety.org/military. The username (login) is guest, and the password is guest (both lowercase, same word). In October, 2014 this web resource will be freely accessible without a password as part of a relaunched Seeking Safety website, at which point the military website will be a sub-page on it.

- Dr. Najavits has had a very strong record of publications, presentations, and other professional activities relevant to the project content (e.g., PTSD, SUD) throughout the study period. See Appendix 3 for a list from 2010-2014.

REPORTABLE OUTCOMES

1. See the Appendix 2 for the journal article (currently under revision for *Military Medicine)*.

2. See the References for a list of presentations of the study's results at multiple scientific presentations at national conferences during the study and Appendix 3 for the associated powerpoint of those results.

3. See Appendix 1 for the list of publications/presentations by the PI during the study period (2010-2014) relevant to the project content (PTSD, SUD, Seeking Safety).

4. See the website www.seekingsafety.org/military for this resulting product of the study (login=guest; password=guest).

CONCLUSION

We successfully met all original scientific goals and SOW tasks by the end of this project. We did need no-cost extension years to accomplish these targets due to multiple factors, including the very slow initial study start-up based on multiple rounds of IRB delays, changes in study staff, loss of some original planned additional study sites, as well as the move of WRNMMC from Washington, DC to Bethesda, MD. Our project resulted in tangible achievements, including a journal article of our results (under revision currently for the journal *Military Medicine)*; numerous presentations at scientific conferences of the study results, a military/veteran Seeking Safety web-page (which has been made available via password access to VA and various DoD sites since it was constructed, and which will be freely available without password protection to anyone as of October 2014 when the Seeking Safety website is relaunched on a new platform). Also, the PI had a very strong record of scientific achievements during the study period related to relevant topics such as PTSD, SUD, and Seeking Safety. Throughout, we maintained all necessary approvals such as IRB and HRPO and obtained clearance for all scientific summaries

of the study results. Our study findings evidenced significant positive outcomes for Seeking Safety at WRNMMC in phase 1, with no difference during phase 2. The latter was contrary to the original study hypothesis, but also results in the conclusion that conducting Seeking Safety "as is" produces positive outcomes, without need for adaptation. This is consistent with findings for Seeking Safety in other settings (e.g., criminal justice, homeless programs, adolescents) which have also found significant positive outcomes without formal adaptation of the model. In addition to the positive quantitative outcomes, feedback from WRNMMC was extremely positive about Seeking Safety, and they have reported that they continue to use the model even after the end of this study and indeed have been expanding its use (such as with their military sexual trauma program). In sum, Seeking Safety evidenced positive outcomes during this pilot study, attained strong satisfaction from both patients and study clinicians, was sustained after the study (indicating positive adoption by WRNMMC), all of which support its use as an excellent fit for DoD treatment for PTSD/SUD.

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2. Presentations directly related to this project are as follows:

American Psychological Association Annual Convention 31 July – 4 August 2013. Our presentation on this study was selected for the prestigious APA President's track and was delivered by Joni Utley, PhD (a postdoctoral fellow of Dr. Najavits).

Walter Reed National Military Medical Center Partial Hospitalization Program & Addiction Treatment Services Program "Innovative Treatments in Military Behavioral Healthcare" Conference on 5 November 2012, presented by Ms. Stephanie Southard.

International Society for Traumatic Stress Studies "Resilience After Trauma: From Surviving to Thriving" Annual Meeting 7-9 November 2013. Currently being reviewed by the WRNMMC IRB, with Dr. Schmitz delivering it.

The 2013 Osteopathic Medical Conference & Exposition in Las Vegas, Nevada, delivered by Ms. Stephanie Southard, BA.

The 2014 Osteopathic Medical Conference & Exposition in Las Vegas, Nevada, delivered by Dr. Cynthia Gragnani.

Dr. Najavits presented on this study at the Feb 1-2, 2011 DoD conference in Fredericksberg, MD.

Dr. Najavits presented a two-hour training on Seeking Safety on March 21, 2011 at the VA/DoD Continuum of Care: Battlefield Healthcare Summit in Washington DC.

Dr. Najavits presented at the national conference, “Complexities and Challenges of PTSD and TBI” held in Boston on Friday, Saturday, and Sunday, July 15-17, 2011 in Boston,

Dr. Najavits presented on July 18, 2011 in Irvine, CA on Seeking Safety at the Institute of Medicine *Prevention, Diagnosis, Treatment and Management of Substance Use Disorders in the U.S. Armed Forces*.

3. Website
www.seekingsafety.org/military for this resulting product of the study (login=guest; password=guest).

APPENDICES

Appendix 1: A list of publications/presentations and other scientific achievvements by the PI during the study period (2010-2014) relevant to the project content (PTSD, SUD, Seeking Safety).

Appendix 2: The journal submission on study results (currently under revision for *Military Medicine)*.

Appendix 3: Examples of powerpoint presentations of the study's results at scientific presentations at national conferences during the study (American Psychological Association and International Society for Traumatic Stress Studies).

Appendix 1: A list of publications/presentations and other scientific achievvements by the PI during the study period (2010-2014) relevant to the project content (PTSD, SUD, Seeking Safety).

New academic appointments

2013-pres.	Adjunct Professor, University of Massachusetts Medical School
2010-pres.	Faculty, VA Center of Excellence (Center for Healthcare Quality, Outcomes and Economics Research), Bedford, MA

Grant Reviews

2011, 2014	National Center for Responsible Gaming, Boston, MA (formerly Kansas City, MO)
2010	Ontario Problem Gambling Research Centre, Toronto, Canada
10/11	NIDA, SBIR Special Emphasis Panel, Scientific Review Group
3/12	Acting Chair, NIDA, SBIR Special Emphasis Panel, Scientific Review Group
11/12	NIMH, Special Emphasis Panel/Scientific Review Group
7/13	Chair, NIH Special Emphasis Panel on PTSD and SUD, Scientific Review Group
11/13	Chair, NIH SBIR Scientific Review Group ZRG1 RPHB-R (12)
11/13	Chair, NIH SBIR Scientific Review Group ZRG1 RPHB-R (13)
12/13	Swiss National Science Foundation, grant reviewer
12/13	Netherlands Organisation for Scientific Research (NWO, the Dutch Research Council), grant reviewer
3/14	Chair, NIH SBIR Scientific Review Group ZRG1 HDM W 10
6/14	Chair, NIH SBIR Scientific Review Group ZRG1 RPHB-R (12) B
6/14	NIH, Review on Social Media and Substance Use and Addiction (R01), 2014/08 ZCA1 SRB-H (O1) R

Editorial Boards:

2009-2011	International Advisory Board, Asian Journal on Gambling Issues and Public Health
2010-pres.	Editorial Board, Addiction Research and Theory
2010-pres.	Editorial Board, European Journal of Psychotraumatology
2010-pres.	Editorial Board, Substance Abuse and Rehabilitation
2011-pres.	Editorial Board, Psychological Trauma: Theory, Research, Practice, and Policy
2014-pres.	Editorial Board, Journal of Dual Diagnosis

Advisory Boards:

2010-pres.	Advisory Board, Project BRIGHT (Building Resilience through Intervention: Growing Healthier Together, Institute for Health and Recovery, Cambridge, MA
2010-2011	The Connection Institute for Innovative Practice, Middletown, CT
2012-pres.	Expert Advisory Panel, Insitute on Trauma and Trauma-Informed Care, University at Buffalo—The State University of New York
2012-pres.	Advisory Board, Center for Gambling Research at the University of Georgia,

	Athens, GA
2013-pres.	National Advisory Board, Spectrum Health Services, Worcester, MA
1998-2013	Advisory Board, National Center for Responsible Gaming, Kansas City, MO (1998-2001); renamed the Institute for Research on Pathological Gambling and Related Addictions, Harvard Medical School, Boston, MA (2001-pres.)
2009-2013	Board of Governors, Veterans Healing Initiative, New York, NY

Journal reviewer

Ongoing reviewer for numerous journals; also the following were new during the study period

2010-pres.	Journal of Trauma and Dissociation
2010-pres.	Psychological Trauma: Theory, Research, and Practice
2010-pres.	American Journal of Orthopsychiatry
2011	Oxford University Press
2011	Women's Health Issues
2011	Institute of Medicine (National Academy of Sciences), peer reviewer for report, "Preventing Violence against Women and Children"
2011-pres.	Journal of Anxiety Disorders
2012	AIDS Research and Treatment
2012-pres.	American Journal on Addictions
2012	Journal of the American Medical Association
2014	Criminal Justice and Behavior

Grants

2010	OPGRC	Ontario Problem Gambling Research Centre – Automated Telephone Screening for Problem Gamblers / PI; $10,000 CD)
2010-2014	VA (CSR&D)	A Randomized Controlled Trial on Women's Substance Abuse Treatment / PI ($626,500 direct, Merit grant)
2010-2013	DoD	PTSD and Substance Abuse / PI ($227,590 total)
2010-2013	DoD	Seeking Safety Therapy for PTSD, TBI, and Substance Use Disorder ($737,734 total) grant #PT090554
2011-2013	VA (CSR&D)	Pilot study of an integrated exposure-based model for PTSD and SUD / Co-PI (Co-PI Krinsley) ($250,726 direct)
2011-2015	VA (HSR&D)	MISSION-Vet HUD VASH Implementation Study / Co-I (PI: Smelson) ($1,098,800 direct)
2013	VA (HSR&D)	Development of a PTSD/SUD program-level assessment / PI ($99,997 direct)
2013-2014	VA (HSR&D)	Assessment of suicide, violence, and related high-risk behaviors in veterans / PI ($99,996)

Other national professional activities

2014	Expert of the month (June) for SAMHSA cable show, "Road to Recovery"
2010	Technical Assistance Consultant, SAMHSA, Trauma-Informed Care, 37 clinical sites

2009-2010 President, American Psychological Association, Society of Addiction Psychology (formerly Division on Addictions) (president-elect 2008-2009; past-president 2010-2011)

Presentations

The PI presented approximately 40 times per year to various government, academic, agency, and private entities. For a complete list see www.seekingsafety.org, section Training.

Publications during the study period (2010-2014)

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Appendix 2: The journal submission on study results (currently under revision for *Military Medicine)*.

Seeking Safety Pilot Outcome Study at Walter Reed National Military Medical Center

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Abstract

Posttraumatic stress disorder (PTSD) and substance use disorder (SUD) are two of the most prominent psychiatric disorders among military service members. Seeking Safety (SS) is an evidence-based behavioral therapy model designed for this comorbidity. This paper reports results of the first study of SS conducted in a military setting. Our pilot trial addressed outcomes, feasibility, and satisfaction. SS was conducted as-is to evaluate its impact without adaptation for military culture. The sample was 24 outpatient service members (from the army, navy, air force, and marines), with 33% minority representation. Inclusion criteria were current PTSD and/or SUD. Ten clinicians participated in this study after receiving SS training. Results showed significant improvements on most outcomes, including *substance use* on the Brief Addiction Monitor**;** *PTSD symptoms* on the PTSD Checklist – Military Version (total and criterion D); and the Trauma Symptom Checklist-40 (sexual abuse trauma index and anxiety subscale); *functioning* on the Sheehan Disability Scale (total and family subscale); *psychopathology* on the Zung Depression Scale total; the BASIS-24 (total and subscales depression functioning, emotional liability, and psychosis); and the Brief Symptom Inventory-18 (total and anxiety subscale); and *coping* on the Coping Self-Efficacy Scale (total). Satisfaction was strong. Discussion includes methodology limitations and next steps.

Posttraumatic stress disorder (PTSD) and substance use disorders (SUD) are some of the most prominent psychiatric disorders among service members [1] [2]. Such disorders are associated with decreased work productivity and social functioning, and increased family problems [3] [4]. Yet they often go untreated due to service members' lack of awareness, stigma, and barriers to receiving mental health services. Positive outcomes are possible for both disorders [5] [6]; thus rehabilitation is the goal.

Seeking Safety (SS) [7] is the first behavioral therapy being tested in the military for co-occurring PTSD and SUD. Per the model developer (the first author of this article), it is also known by the name *Seeking Strength* for populations such as military or first responders who must go into harm's way in their work and thus cannot necessarily always "seek safety" in a literal sense. SS is a resiliency-oriented, cognitive-behavioral therapy approach that provides psychoeducation and coping skills to help clients attain greater strength and safety in their lives. As a present-focused treatment, it does not require clients to describe past trauma. It promotes stabilization and emphasis on current functioning, goals that are highly prized in military settings. The treatment is designed for flexible use: for any type of trauma and substance, both genders, in group or individual format, and any treatment setting. SS addresses cognitive, behavioral, interpersonal, and case management domains. It has 25 topics, each addressing a safe coping skill, such as *Honesty; Taking Good Care of Yourself; Recovery Thinking; Asking for Help; Healing from Anger;* and *Creating Meaning*. Topics can be conducted in any order, using as few or as many as are possible within the available timeframe.

SS is established as an evidence-based treatment using standard criteria in the field [naj/hien]. There are over twenty completed outcome studies on Seeking Safety, including pilots, randomized controlled trials (RCTs), and multisite trials. SS has evidenced consistent positive impact in reducing substance use, trauma-related symptoms, and other problems [5, 8]. It is the only model tested thus far that to decrease both PTSD and SUD by end of treatment compared to a control condition [5]. Such findings are especially notable in light of recent RCTs of exposure-based (past-focused) PTSD therapies in PTSD/SUD samples, which thus far have not outperformed any control by end of treatment on either PTSD or SUD [9].

In the past decade, a greater focus on evidence-based practice in the Department of Defense has aimed to increase the quality and impact of psychiatric care from the battlefield to tertiary care medical facilities. The current pilot study is part of that broader mission. Our goal was to evaluate SS in a military setting, with a focus on outcomes, feasibility, and satisfaction.

Method

Setting. Walter Reed National Military Medical Center (WRNMMC) is the top tertiary care destination for military health care, providing comprehensive services in over 100 clinics and specialties, for military beneficiaries from across the country and internationally. Within WRNMMC, the Psychiatry Continuity Service (PCS) and Addiction Treatment Service (ATS) offer a wide range of evidence-based treatment modalities, including Seeking Safety, as part of their mental health services. The PCS is a tertiary referral resource that provides both adult partial hospital and intensive outpatient levels of care for active duty service members, of whom approximately 50% have been deployed to an area of combat operation. The ATS provides outpatient substance abuse services for active duty personnel, eligible dependents, and retirees, 18 years and older.

Protocol. As part of a grant-funded research study, our plan was to evaluate the impact of SS when conducted as-is, with no specific adaptation for the military environment. Recruitment occurred from May 2011 to June 2012. The study protocol was approved by the WRNMMC Institutional Review Board (IRB) and the Department of Defense Human Research Protection Office. SS was conducted in individual and group modality, with the latter in open group format. Sessions lasted 60 – 90 minutes and were conducted once or twice per week (the former for individual sessions and the latter for group). Participants were encouraged to attend

as many of the 25 Seeking Safety treatment topics as possible within their length of stay, which was typically 3 to 4 weeks.

Patients. Twenty-four service members comprised the patient sample, recruited from the PCS and ATS programs via word-of-mouth and chart review. All had to have current PTSD and/or substance use disorder per DSM-IV-R. Exclusions were current psychosis; untreated bipolar I disorder; and major intellectual disability or traumatic brain injury that would prevent comprehension of written materials. Inclusion / exclusion criteria were kept minimal to achieve a sample typical of real practice. To be included in the final analyzable sample, the service member had to attend at least eight sessions of SS, each a different topic from the SS manual. Eight sessions was defined a priori as the minimum dose to evaluate the impact of SS, representing about one-third of the treatment and below which it would be difficult to ascribe outcomes to the intervention.

SS clinicians. Ten clinicians conducted SS, nine female. Seven were from PCS and three from ATS. All had prior experience treating at least one or more service members with PTSD and/or SUD. Seven were social workers, and one each psychiatrist, psychologist, recreational therapist, and art therapist. Their average clinical experience was 10.9 years (SD=8.62). Clinicians were trained by a certified SS instructor in a one-day workshop or by viewing the 4-hour SS training videos. Both options were followed by two hours of phone consultation by the SS instructor. The SS instructor evaluated fidelity using the SS Adherence Scale [10] based on session audiotapes and/or telephone role-plays of full-length SS sessions.

Measures. Data collection occurred at baseline, session 8 of SS, and end of treatment just after the last Seeking Safety session. Unless indicated otherwise, all measures were collected at all three timepoints, are self-report, have psychometric validation, and are scaled such that higher scores indicate greater impairment. Measures were scored as specified by the scale developer. If a total score was needed rather than a mean, missing data was handled by taking the sum of the answered questions divided by the number of answered questions, and multiplying by the number of items on the scale.

(a) *Patient measures*

Substance use. The Brief Addiction Monitor [11] has 17 items rated for the past month. It has three subscales: use (scaled 0-12) measuring number of days of use per substance; risk (scaled 0-24), i.e., factors associated with increased substance use, such as psychological problems, craving, and risky situations; and protection (scaled 0-24), i.e., factors associated with decreased substance use, such as social support and 12-step group attendance. A higher score on the latter subscale indicates less pathology.

Trauma and PTSD. The Stressful Life Experiences Screening Questionnaire (SLEQ; [12] identifies lifetime exposure to 20 types of trauma, each scaled 0 – 10 for the extent to which the item "describes your experience" (0=did not experience this, to 10=exactly like my experiences). Items endorsed at the midpoint of 5 or higher were identified as positive responses. The PTSD Checklist--Military Version (PCL-M; [13] has 17 items to assess PTSD symptoms in the past month (scaled 1-5). The Trauma Symptom Checklist-40 (TSC-40; [14] has 40 items to assess trauma-related symptoms in the past two months (scaled 0-4).

Functioning. The Sheehan Disability Scale [15] has 5 items assessing functioning in work/school, social life, and family life/home responsibilities in the past week (scaled 1-10). Higher scores indicate better functioning.

Coping. The Coping Strategies Inventory [16] has 18 items to measure adaptive and maladaptive coping styles in the past month (scaled 1-5). The Coping Self-Efficacy Scale [17] has 26 items of perceived ability to cope with challenges in the past month (scaled 0-10). On both measures, higher scores indicate better functioning.

Psychopathology. The Brief Symptom Inventory (BSI; [18] has 18 items assessing psychological symptoms in the past week (scaled 0-4). The Zung Depression and Anxiety Scale [19] has 20 items to measure depression and anxiety in the past several days (scaled 1-4). The Behavior

and Symptom Identification Scale (BASIS-24; [20] has 24 items to assess symptoms and functioning in the past week (scaled 0-4).

(b) *Clinician assessments.* At baseline, the Clinician Background Questionnaire identified professional characteristics [21]. The PTSD/SUD Treatment Knowledge Test is 27 questions to evaluate learning of information from the SS manual [22]. The Protocol Implementation Questionnaire has 16 items measuring clinicians' views of a manualized treatment, in this case SS scaled 0-100% [23].

(c) *Patient and clinician measures.* The Clinical Global Impressions Scale [24] was used to rate patients' level of improvement since baseline (scaled 1=very much improved to 7=very much worse). The SS End-of-Session Questionnaire from the SS book was collected to obtain feedback at the end of each session, with 6 (scaled 0-3). The Seeking Safety End of Treatment Questionnaire [25] was collected at session 8 and end of treatment to measure how how helpful SS treatment components were, with 59 items (scaled -3 to +3). On the latter two measures, higher scores indicate more positive views.

Data analysis. We used mixed effects modeling as our primary analytical approach to account for the clustered structure of the data (i.e., repeated assessments within an individual). Specifically, we used Mixed Model Analysis of Variance (MMANOVA) [26], which models all available data for each participant and is thus useful for datasets such as ours where some measures were collected more frequently than others. To address non-normality, square or square root transformations [27] were applied to improve the approximation of normality. For effect size calculations, we used Cohen's D to compare two timepoints (pre- versus post-treatment); for variables with more than two timepoints, we used eta-squared as the latter does not assume linear change over time. Effect sizes are interpreted using standard benchmarks [28]. For Cohen's D, .8 is large, .5 is medium, and .2 is small; for eta-squared, .14 is large, .06 is medium, and .01 is small. Finally, for one variable on one measure, the BAM use subscale, we used generalized estimating equation (GEE) methodology [29], which analyzes longitudinal binary responses, as well as count data, while addressing the clustering of the data attributable to the repeated measures within a subject. For the GEE analysis, effect size is identified using the odds ratio extended from Cohen’s classification [30], which for any effect size over 1.0 has thresholds of 1.5 for small, 2.5 for medium, 4 for large, and 10 for very large.

Results

Sample characteristics. Of the patient sample (n=24), 66.7% were male, 25% were married, 58.3% had attended college, and the average age was 28.9 years (SD=8.77). Ethnicity was 66.7% White, 25% African-American, 4.17% Hispanic or Latino, and 4.17% more than one race. Four military branches were represented: 46% army, 25% navy, 17% marine, and 12% air force. In terms of trauma history on the SLEQ, patients reported a mean of 7.00 (SD=3.31, n=24 traumas. The most frequent (average score greater than 5 on the 10-point scale) were: witnessed or experiences a serious accident or injury (n=20); witnessed or experience a death of close friend or family member other than spouse or child (n=20); witnessed or experienced a life threatening illness (n=18); saw or handled dead bodies other than at a funeral (n=15); was involved in combat or war or lived in a war affected area (n=12); felt responsible for the serious injury or death of another person (n=11); witnessed or experienced a natural disaster (n=10); witnessed or was attacked with a weapon other than a combat or military setting (n=10); witnessed someone else being choked, hit, spanked, or pushed hard enough to cause injury (n=10).

The clinician sample (n=10) was 90% female; an average age of 36.2 years (SD=11.40); and 10.9 (SD=8.62) years of clinical experience. Ethnicity was 50% White, 40% African-American, 10%. Most (60%; n=6) had a master’s degree; one (10%) had an MD; and one (10%) had a doctoral degree. Clinicians reported a mean of 126.66 hours (SD= 176.07, n=9) conducting SS groups prior to the study, and 0 hours conducting SS individually prior to the study.. The latter

large mean represented a bi-modal sample in which four clinicians reported no hours and four reported over 100 hours.

Attendance. Patients attended an average of 11.17 Seeking Safety sessions (SD = 2.99). All had access to at least eight sessions of SS and beyond that available dosage varied based on length of stay. Most patients (n=18; 75%) completed nine sessions or more and 6 subjects (25%) had the minimum 8 sessions to be included in the project. One participant attended 7 sessions and thus did not meet the 8-session minimum dosage to be included in the analysis.

Outcomes. See Table 1. Of the 32 outcome variables analyzed, 15 (46.9%) were significant ($p < .05$), far exceeding the number expected by chance (1.6, i.e., 5% of 32). Nine of the 32 variables (28.1%) were trends ($p=.05$ to $p < .10$) and 8 were not significant (25%). Non-significant variables were the BAM subscales risk and protection; the PCL-M cluster C; Basis-24 subscales self-harm and substance abuse; Coping Strategies Inventory mean; TSC-40 dissociation subscale; and BSI-18 somatization subscale.

Perception of improvement. On the Clinical Global Impressions Scale, which was not an outcome measure per se as it was not collected at baseline, both patients and clinicians reported a perception that patients' had improved from baseline to session 8 (patients x=2.83, SD=1.20; clinicians x=2.86, SD=.79) and to end of treatment (patients x=2.00, SD=1.00; clinicians x=2.00, SD=1.00).

Treatment satisfaction. Table 2 provides the ratings by clinicians and clients on the SS End of Session Questionnaire, indicating consistent positive ratings. On the Seeking Safety Feedback Questionnaire, both patients and clinicians rated the treatment positively overall at session 8 (patient M=2.13, SD=.80; clinician M=2.30, SD=.48) and end of treatment (patient M=2.40, SD=.56; clinician M=2.40, SD=.56).

Clinician measures. On the Protocol Implementation Questionnaire, clinicians reported high ratings of perceived ability to conduct Seeking Safety (M=90.00, SD=7.07), satisfaction with Seeking Safety (88.00, SD= 6.70), and comfort implementing Seeking Safety (89.60, SD=9.53). The mean score of clinicians (out of 30 points) on the PTSD/SUD Treatment Knowledge Test was 22.22 (SD=1.72, n=9) at pre-treatment, 20.56 (SD=3.43, n=9) at session 8, and 21.50 (SD=3.70, n=4) at the end of treatment, with no significant change over time.

Discussion

This is the first outcome study we know of to evaluate any therapy for PTSD/SUD in a military setting. Strengths of this pilot trial include representation from four major military branches; the use of a psychometrically validated instruments; a one-third minority rate in the patient sample; the use of a relatively large number of clinicians; and rigorous statistical analyses.

We found positive results for most of the variables tested. These included domains of substance use, PTSD symptoms, functioning, psychopathology, and coping. Effect sizes, which indicate the degree of change, were generally in the medium to large range. Our finding of a significant improvement on both PTSD and substance use is especially important as thus far most models tested for PTSD/SUD populations have not shown impact on both [5]. Also, in military medical settings, it is known to be challenging to obtain positive self-report of substance use and difficult therefore to show change in that domain.

Our results are notable given that SS was conducted in a short timeframe averaging 11 sessions. Military hospitals often have short lengths of stay for PTSD and/or SUD, and thus there is a need for models that are feasible within such timeframes. Feasibility was also shown by our successful engagement of clinicians who were native to the setting rather than brought in from the outside [naj/hien]. The clinicians were able to achieve competence in conducting SS in relatively low-cost ways in terms of amount of training they received. In general, the use of an integrated model for PTSD and SUD, such as SS, may also enhance efficiencies of cost and workforce allocation as both disorders are treated by the same clinician rather than two

separate clinicians. In this study, too, we found that clinicians drawn from both a SUD and mental health clinic were equally able to learn SS.

Satisfaction with SS was strong and aside from the quantitative data, informal qualitative comments by staff, clients, and program administrators indicated clear feedback that SS fits well in the military treatment environment. Because it is a present-focused, coping skills approach, it does not require patients to tell the narrative of their trauma, which can be emotionally difficult for some patients to tolerate, and can be contraindicated in the context of current SUD [x]. The resiliency-oriented nature of SS also fits well with the military focus on rapid return of service members to duty. Finally, the fact that SS content addresses both PTSD and SUD means that it can be conducted readily in both mental health and substance abuse programs, as was done in this trial.

Next steps include the need for a randomized controlled trial to evaluate SS against a control condition and a larger sample size. Such next steps in scientific rigor could help understand issues we were not able to address in this pilot, such as patient and clinician characteristics that might predict of who does best with SS; and whether some symptoms are quicker to change or moderate outcomes more than others.

In general, more research is needed on military service members with PTSD/SUD. These disorders are some of the most prominent psychological wounds of war. This comorbidity is elevated in military populations, has known serious clinical impact, and often presents challenges to both patients and their clinicians [iom]. In the current era there is greater emphasis than ever before on rapidly and aggressively addressing psychological problems before they become chronic [c]. This is progress in and of itself, but it remains a tall task to actually achieve the level of improvement that these service members need and so deserve after all that they have given.

Table 1: Outcomes[1]

	Baseline	Session 8	End-of-Treatment	Across Time (Fixed Effects)	Effect size
	Mean (SD)	Mean (SD)	Mean (SD)	F (df), p	Eta squared
PTSD Checklist-Military					
Total score	57.68 (14.33)	50.66 (17.37)	36.63 (17.82)	4.54 (2, 8.65), .045	.18 (large)
Cluster B	15.96 (6.43)	14.58 (6.21)	10.00 (5.87)	3.27 (2, 12.12), .073†[2]	.23 (large)
Cluster D	18.35 (4.73)	15.79 (5.37)	9.55 (2.60)	19.51 (2, 14.60), <.001	.05 (small)
Trauma Symptom Checklist-40					
Mean	1.37 (.47)	1.32 (.58)	0.71 (.58)	4.39 (2, 7.52), .054†	.18 (large)
Anxiety	1.16 (.52)	1.10 (.61)	0.49 (.49)	6.48 (2, 18.95), .007	.12 (medium)
Sexual abuse trauma index	1.28 (.59)	1.41 (.61)	0.80 (.65)	4.53 (2, 11.93), .034	.17 (large)
Sleep	2.28 (.59)	2.17 (.65)	1.23 (.89)	3.09 (2, 9.53), .093†	.24 (large)
Depression	1.65 (.58)	1.39 (.74)	.78 (.75)	4.73 (2, 5.56), .063†	.17 (large)
Sexual problems	.95 (.67)	.89 (.65)	.60 (.63)	4.13 (2, 8.47), .06†	.19 (large)
Zung Depression Scale					
Total	56.56 (9.77)	51.76 (13.06)	42.21 (12.24)	6.38 (2, 5.06), .041	.14 (large)
BASIS-24					
Total	36.39 (15.53)	35.08 (17.39)	20.75 (11.88)	8.04 (2,18.31), .003	.10 (medium)
Depression functioning	13.76 (5.23)	12.13 (4.90)	6.12 (4.81)	12.04 (2, 9.49), .002	.07 (medium)
Emotional liability	7.00 (2.98)	6.38 (2.87)	3.60 (1.34)	5.27 (2, 14.15), .019	.15 (large)
Psychosis	4.17 (3.35)	4.08 (3.94)	1.87 (1.61)	8.12 (2, 36.24), .001	.08 (medium)
Relationships	8.19 (4.78)	8.42 (5.47)	5.80 (5.40)	3.46 (2, 9.13), .076†	.21 (large)
Coping Self-Efficacy Scale[3]					
Mean	122.11 (53.62)	135.17 (53.09)	194.00 (60.78)	7.51 (2, 10.11), .010	.11 (medium)
Sheehan Disability Scale					
Total	21.83 (7.40)	18.08 (8.40)	12.60 (9.04)	5.05 (2, 13.76), .023	.16 (large)
Family	6.57 (3.41)	6.17 (2.99)	2.80 (1.92)	4.84 (2, 15.95), .023	.16 (large)

Social	7.52 (2.98)	6.04 (3.16)	4.80 (3.90)	3.03 (2, 23.55), .067†	.24 (large)
Work/school	7.74 (2.73)	5.88 (3.26)	5.00 (4.18)	3.22 (2, 12.92), .073†	.23 (large)
Brief Symptom Inventory-18					
Mean	2.76 (.82)	2.52 (.89)	1.68 (.68)	6.10 (2, 8.41), .023	.14 (large)
Anxiety	3.06 (1.02)	2.67 (1.01)	1.55 (.46)	14.58 (2, 14.69), <.001	.06 (medium)
Depression	3.03 (1.10)	2.75 (1.20)	1.90 (1.17)	3.84 (2, 8.49), .065†	.20 (large)
Brief Addiction Monitor					
Use [of substances]	1.83 (2.86)	.59 (1.48)	0	4267.91 (1), <.001[4]	Cohen's D: 2.27 (small)[5]

[1]For non-significant results, see text.

[2] † symbol indicates a trend

[3]Higher score indicates more positive coping.

[4]GEE analysis, Wald Chi-square, see data analysis for explanation

[5] Odds ratio for GEE analysis, see data analysis for explanation. The parameter estimates and standard error were 41.80 and .64, respectively.

Table 2: Seeking Safety satisfaction ratings: End-of-Session Questionnaire[1]

	Client ratings mean (SD)	n[2]	Clinician ratings: mean (SD)	n[2]
How helpful was the session?	2.05 (.91)	489	2.56 (.63)	249
How helpful was the quotation?	1.77 (1.05)	540	1.82 (.86)	273
How helpful was the therapist?	2.34 (.86)	542		
How helpful was the SS topic?				
Introduction	1.86 (1.02)	36	2.52 (.63)	31
Safety	2.04 (.87)	63	2.59 (.72)	39
PTSD: taking back your power	2.45 (.78)	29	2.53 (.63)	17
Grounding	2.16 (.86)	31	2.61 (.51)	13
When substance control you	2.96 (.97)	17	2.86 (.38)	7
Asking for help	2.55 (.60)	22	3.00 (.00)	11
Taking good care of yourself	2.39 (.85)	18	2.63 (.74)	8
Compassion	1.93 (1.13)	29	2.67 (.50)	9
Red/green flags	2.20 (.82)	25	2.71 (.47)	14
Honesty	2.23 (1.07)	26	2.91 (.30)	11
Recovery thinking	2.21 (1.13)	19	2.33 (.79)	12
Integrating the split self	1.90 (.87)	29	2.50 (.71)	10
Commitment	2.16 (.60)	19	2.83 (.41)	6
Creating meaning	2.13 (.92)	23	2.77 (.60)	13
Community resources	1.92 (.86)	13	2.29 (.76)	7
Setting boundaries in relationships	2.24 (.75)	17	2.88 (.35)	8
Discovery	2.18 (1.17)	11	2.00 (.82)	7
Getting other to support your recovery	1.86 (.86)	14	2.71 (.49)	7
Coping with triggers	2.11 (.94)	19	2.67 (.50)	9
Respecting your time	1.92 (1.00)	12	2.33 (.82)	6
Healthy relationships	2.50 (.71)	10	2.80 (.45)	5
Self-nurturing	2.25 (.90)	24	2.89 (.33)	9
Healing from anger	2.41 (.87)	17	2.56 (.73)	9
The life choices game	2.38 (.75)	8	2.50 (.58)	4
Termination	2.33 (1.21)	6	2.71 (.49)	7

[1]Scaled from 0 (not at all) to +3 (a great deal).
[2]Refers to number of sessions rated.

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Appendix 3: Examples of powerpoint presentations of the study's results at scientific presentations at national conferences during the study (American Psychological Association and International Society for Traumatic Stress Studies).

Seeking Safety Pilot Outcome Study at Walter Reed National Military Medical Center

ISTSS Annual Convention

November 9, 2013

Lisa M. Najavits, PhD, Gregory Lande, DO,
Cynthia Gragnani, PhD, Debra Isenstein,
LCSW-C, MAC, Stephanie Southard, LCSW,
Martha Schmitz, PhD, ABPP

Agenda

- Seeking Safety/Seeking Strength
- Walter Reed National Military Medical Center (WRNMMC) Study
- Next Phase: Clinical Adaptations of Seeking Safety per Military Supplement

What is Seeking Safety?

- Evidence-based, manualized, integrated treatment for co-occurring PTSD/SUD

- Also has been used to help those:
    - With 1 or the other disorder
        - Subthreshold PTSD and/or SUD
        - A history of PTSD/SUD
        - As a general stabilization model to build coping skills generally

What is Seeking Safety?

- Alternate title: Seeking Strength
- Focuses on the theme of safety, with 25 cognitive, behavioral, and interpersonal skills to address both disorders at the same time (integrated therapy), from the start of treatment (1st stage therapy)
- Most empirically studied and widely adopted model for PTSD/SUD

- **What is Seeking Safety?**

- Examples of Topics (of 25 total):
  - Introduction/Case Management
  - Safety
  - PTSD: Taking Back Your Power
  - Substance Abuse
  - Asking for Help
  - Detaching from Emotional Pain (Grounding)
  - Setting Boundaries in Relationships

- Examples of Coping Skills (countless):
  - Persistence
  - When in doubt, do what's hardest
  - Avoid avoidable suffering
  - Move toward your opposite

- **Seeking Safety Evidence**

- Studies (over 20) have generally included chronic/severe clients, including those with: substance dependence, drug use disorders, homeless, those with suicidal ideation or self-injurious behaviors

- All studies have had positive outcomes in various areas: trauma-related symptoms ,substance use, suicidality, problem solving, social skills, cognitions, overall functioning, HIV risk behavior

- In 6 of 7 comparisons to treatment-as-usual controls, Seeking Safety superior on various domains

- "Strong research support "for PTSD with SUD – Division 12, APA
- "Strong research support" for adults & "modest research support" for adolescents for SUD – Division 50, APA
- Level A (highest level of evidence) - ISTSS

- **WRNMMC Study - Introduction**

- Seeking Safety conducted “as is” at Walter Reed

- Evaluated for implementation in military setting

- Goals:
  - To determine if adaptations were needed for working with military
  - To gather information about implementation, satisfaction, and
  - feasibility

- **WRNMMC Study - Method**

- Study conducted at 2 clinics from May, 2011 – June, 2012:
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- 24 service members recruited who attended at least 8 Seeking Safety sessions
- Seeking Safety sessions were conducted in groups (rolling enrollment) and individually
- All 25 topic attendance encouraged
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- 10 therapists trained in Seeking Safety conducted the treatment
- An independent rater assessed fidelity using the Seeking Safety Adherence Scale (Najavits, 2003)

WRNMMC Study Method: Measures

• Feedback was collected from both service members & therapists via qualitative and quantitative methods

- Baseline
- Mid-treatment (8 Seeking Safety topics)
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- • Brief Addiction Monitor
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- **WRNMMC Study, Next Phase: Clinical Adaptations**

- Development of a written supplement to include clinical guidelines in using SS with military population
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- **WRNMMC Study, Next Phase: Clinical Adaptations**

- Quotes Adapted for Military Culture
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- **Conclusions**

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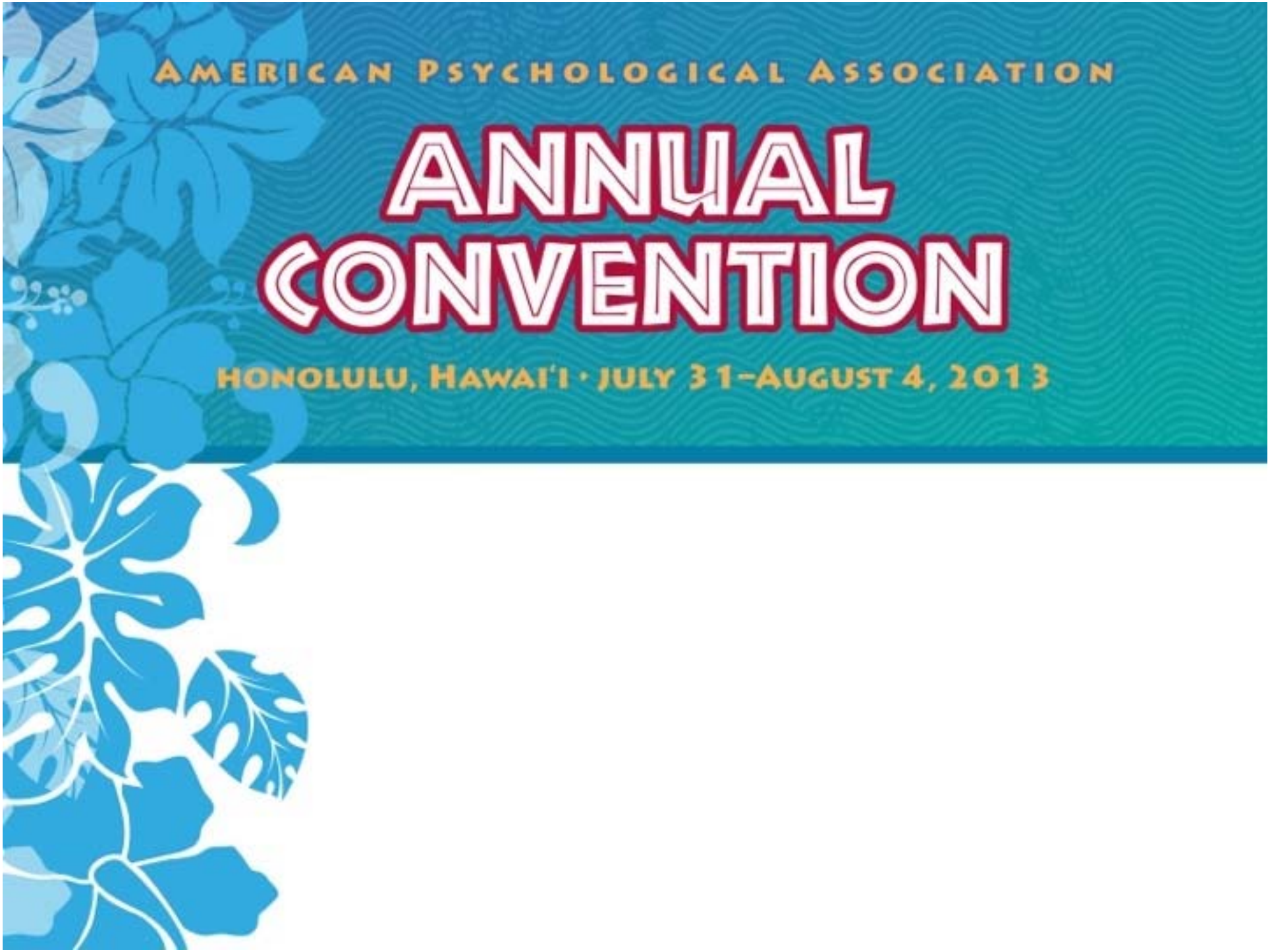
AMERICAN PSYCHOLOGICAL ASSOCIATION
ANNUAL CONVENTION
HONOLULU, HAWAI'I · JULY 31–AUGUST 4, 2013

Seeking Safety for Service Members

APA
ANNUAL
CONVENTION
JULY 31–AUGUST 4
HONOLULU, HAWAI'I

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